clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 10

Administrative practice and procedure, News media.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and authority delegated to the Commissioner of Food and Drugs, 21 CFR part 10 is amended as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

1. The authority citation for 21 CFR part 10 continues to read as follows:

Authority: 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

2. Section 10.75 is amended by redesignating paragraph (b) as paragraph (b)(1) and by adding paragraph (b)(2) to read as follows:

§ 10.75 Internal agency review of decisions.

* * * * *

(b)(1) * * *

(2) A sponsor, applicant, or manufacturer of a drug or device regulated under the act or the Public Health Service Act (42 U.S.C. 262), may request review of a scientific controversy by an appropriate scientific advisory panel as described in section 505(n) of the act, or an advisory committee as described in section 515(g)(2)(B) of the act. The reason(s) for any denial of a request for such review shall be briefly set forth in writing to the requester. Persons who receive a Center denial of their request under this section may submit a request for review of the denial. The request should be sent to the Chief Mediator and Ombudsman.

Dated: November 12, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–30812 Filed 11–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 97N–0524]

RIN 0910–AA43

Food Labeling: Warning and Notice Statement: Labeling of Juice Products; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration is correcting a final rule that appeared in the **Federal Register** of July 8, 1998 (63 FR 37030). The final rule revised the food labeling regulations to require a warning statement on fruit and vegetable juice products that have not been processed to prevent, reduce, or eliminate pathogenic microorganisms that may be present. The document was published with several inadvertent editorial errors. This document corrects those errors.

DATES: The regulation is effective September 8, 1998; however, compliance for juice other than apple juice and apple cider is not required until November 5, 1998.

FOR FURTHER INFORMATION CONTACT: Geraldine A. June, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

In FR Doc. No. 98–18287, appearing in the **Federal Register** of Wednesday, July 8, 1998, the following corrections are made:

1. On page 37038, in the third column, in the fourth full paragraph, in the sixth line, ''(Ref. 9)'' is corrected to read ''(Ref. 7)''.

2. On page 37040, in the first column, in the last line of the first full paragraph, ''(Ref. 10)'' is corrected to read ''(Ref. 8)''.

3. On page 37040, in the third column, in the second full paragraph, in the eleventh line, ''(Ref. 11)'' is corrected to read ''(Ref. 9)'' and in that same paragraph, in the fifteenth and eighteenth lines, ''(Ref. 12)'' is corrected to read ''(Ref. 10)''.

5. On page 37041, in the last line of the third column, ''(Ref. 13)'' is corrected to read ''(Ref. 11)''.

6. On page 37044, in the third column, in the fourth paragraph, in the twenty-fifth line, ''(Ref. 14)'' is corrected to read ''(Ref. 12)''.

7. On page 37047, in the second column, in the second full paragraph, in the twentieth line, ''(Ref. 15)'' is corrected to read ''(Ref. 13)''.

§ 101.17 [Corrected]

8. On page 37056, in the third column, in § 101.17(g)(7)(i)(B), beginning in the fourth line, ''Hazard Analysis Critical Control Points'' is corrected to read ''Hazard Analysis and Critical Control Point''.

Dated: November 10, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–30814 Filed 11–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Fenbendazole Suspension; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulation concerning veterinary prescription use of Hoechst Roussel Vet's fenbendazole suspension for cattle. The amendment clarifies the oral dose of fenbendazole suspension used as a dewormer in cattle.

EFFECTIVE DATE: November 18, 1998.

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7575.

SUPPLEMENTARY INFORMATION: Hoechst Roussel Vet, 30 Independence Blvd., P.O. Box 4915, Warren, NJ 07059, is sponsor of new animal drug application (NADA) 128–620 that provides for oral, veterinary prescription use of Panacur® (fenbendazole) 10 percent suspension. The drug is used as a dewormer in cattle, including dairy cattle of breeding age at 5 milligrams per kilogram (mg/kg) of body weight, and only in beef cattle at 10 mg/kg of body weight. The regulations are amended in 21 CFR 520.905a to clarify the approval.

The amendments clarify the drug dose used to treat various classes of animals and insert certain technical revisions. No additional safety or effectiveness data were required. A revised freedom